UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,053	12/16/2004	Yoshihiro Urade	URADE2	3496

1444 7590 07/15/2008

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
07/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,053	URADE ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-8* is/are pending in the application.

4a) Of the above claim(s) *2,3 and 6-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This Office Action is in response to the amendment submitted on 03/19/08. Claims 1-3 and 5-8 are currently pending in the application, with claims 2-3 and 6-8 having being withdrawn and claim 4 having being cancelled. Accordingly, claims 1 and 5 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Applicant's traversal with respect to claims 1 and 4-5 as being definite has been fully considered. Given applicant's cancellation of claim 4 and its incorporation into claim 1, Examiner concludes that the claims are now definite. Thus, the rejection of claims 1 and 4-5 under 35 U.S.C. § 112, second paragraph has been withdrawn.

Applicant's arguments that Tona never described the relationship between malarial activity and the compounds from G. Kola have been fully considered but are not found persuasive. Applicant's invention is to a pharmaceutical composition and regardless if Tona describes such composition specifically for the use of anti-malerial activity is immaterial given that an intended use in a product claim is not afforded patentable weight. Examiner further points out that a recitation of the intended use of

the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the limitation of the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963*). Thus, the intended use of for the treatment of malaria is not afforded patentable weight.

Applicant's argument that Tona suggests the uses of xanthones for anti-malarial activity and not biflavonoids and that the compositions of Tona is from G. Kola bark and not from seeds has been fully considered but is not found persuasive. Tona clearly teaches that in certain cultures, the seeds are known to be chewed for days on end for its efficacy against malaria (see pg. 198, right col., bottom). Moreover, table 1 in Tona (pg. 194, table 1, G. Kola Heckel; Sd=Seed extracts A & B) clearly shows that the seeds of G. kola were also extracted and showed enhanced anti-malarial inhibition (see pg. 196, table 2, g. kola, Sd=seed and col. 1-2). Finally, Tona teaches a variety of potential compounds that may be responsible for the anti-malerial effect including biflavonoids (see pg. 199; left col. top). Though Tona did not explicitly state the actual compounds found in his ethanolic extract, Okunji et al. was provided to demonstrate that the ethanolic extract contains GB1 (i.e. applicant's elected compound of claim 5) along with other compounds which suggests that GB1 is inherently included in the ethanolic fraction of Tona. Again, Examiner points out that the claims are directed to a

pharmaceutical composition containing GB1 or a compound of similar formula and Tona as evidenced by Okunji et al. clearly anticipates applicant's invention as Tona teaches an ethanolic extract of G. kola and Okunji shows evidentiary support that GB1 is an inherent part of the ethanolic extracts as GB1 along with three other compounds are the major constituents of the ethanolic extracts of G. kola. Consequently, the rejection of claims 1 and 4-5 were indeed proper.

Applicant's argument that Okunji et al. does not teach or suggest the relationship of biflavones and anti-malerial effect has been fully considered but is not found persuasive. Again, Examiner reiterates the fact that Okunji et al. was provided as evidentiary support that the ethanolic extract of Tona inherently contains GB1 or 2S, 3R, 2'S, 3'R-5, 7,3',5'7'-pentahydroxy-2,2'-bis-(4-hydroxphenyl)-2,3,2',3'-tetrahydro[3,8']bichromeyl-4,4'-dione as one of the four major constituents found in G. kola. Thus, given that Tona teaches ethanolic extracts of G. kola seeds and Okunji et al. teaches GB1 as one of the major constituents of G. kola seed extracts, Tona as evidenced by Okunji et al. does indeed anticipate applicant's invention.

For these reasons, the rejection of claims 1 and 4-5 under 35 U.S.C. § 102 (b) remains proper. However, in view of applicant's amendment and cancellation of claim 4, the following modified 102 (b) Final rejection is being made.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Tona et al. (J. of Ethnophar. 68 (1999), pgs. 193-203, previously submitted) as evidenced by Okunji et al. (Planta Med. 68 (2002), pgs. 440-444), previously submitted.

The inclusion of the terms "*for the treatment of malaria*" in applicant's invention is an intended use and as such is not afforded patentable weight in a product claim. It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the limitation of the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963*). Thus, the intended use of ** is not afforded patentable weight.

Tona et al. discloses the use of plant extracts from the Garcinia kola Heckel plant species for the treatment of malaria (see abstract, pg. 193). In particular, 50 mg of plant seed powder were macerated with 300 ml of Ethanol (i.e. pharmaceutical carrier) for 24h, filtered and evaporated in order to yield dried extracts denoted as extracts A (see Preparation of crude extracts, pg. 194). Subsequently, an in vitro antiplasmodial activity test was performed utilizing 2 µg/ml to 2 mg/ml concentrations of extract A on infected blood suspensions where Garcinia kola seed extract A caused an 82.7% inhibition of P. falciparum growth (see table 2, pg. 196). Though Tona et al. did not specifically disclose the biologically active constituents present in its extracts, they did however suggest the antimalarial effects in the seeds of G. kola and further contended that these effects may be attributed to the presence of various biologically active components including flavonoids, biflavonoids, and xanthones (see pg. 198, lines 40-44, right column; and pg. 199, left column, lines 2-6).

Okunji et al. has been provided as evidence that the biflavones characterized as GB1 (i.e. instant claim 5; 2S, 3R, 2'S, 3'R-5,7,3',5', 7'-pentahydroxy- 2, 2'-bis-(4-hydroxyphenyl)-2,3,2',3'-tetrahydro[3,8']bichromeyl-4,4'-dione, GB2, GB1-glycoside and kolaflavanone are the main biologically active components of the Garcinia kola seeds (see table 3, pg. 443), with GB1 being the major constituent and in higher concentrations in the ethanolic fractions (see abstract, fig.1 Materials and Methods section, left column and procedures right column, pg. 441).

Accordingly, the teachings of Tona et al. anticipate claims 1 and 5.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L./

Examiner, Art Unit 1617

07/08/2008

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617